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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,480	10/23/2003	Silviu Itescu	0575/66602-B/JPW/BJA	2572

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John P. White
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER	
BOWMAN, AMY HUDSON	
ART UNIT	PAPER NUMBER
1635	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/693,480	ITESCU, SILVIU	
	Examiner	Art Unit	
	Amy H. Bowman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,10,14,16-20,24,35-37 and 43-50* is/are pending in the application.

4a) Of the above claim(s) *1,10,14,16-20,and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *35-37 and 43-50* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

This is a supplemental restriction requirement necessitated by the amendments to the claims filed on 1/8/2007. It is noted that the instant response to this election/restriction requirement must be consistent with the election/restrictions in the response filed on 1/8/07, where applicant elected group V and "intramyocardially" with traverse.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 35-37, 43-46, 49 and 50, drawn to a method of treating a subject suffering from a disorder of a tissue involving loss or apoptosis of cells of the tissue which comprises administering to the subject a composition comprising an amount of an agent, wherein the agent comprises human stromal-derived factor-1α which induces activation of CXCR4, the composition being administered in an amount effective to cause proliferation of the cells or inhibition of apoptosis of the cells of the tissue within the subject so as to thereby treat the subject, classified in class 514, subclass 1. **Election of this group also requires the further species election of a single disorder from the group consisting of myocardial infarction, congestive heart failure, chronic ischemia, ischemic disease, diabetic heart disease or cardiomyopathy, as explained below AND the further species election of a single mode of administration selected from the group consisting of**

intramyocardially, systemically, intracoronarily, via a stent, via a scaffold or via slow release formula.

II. Claims 35-37, 43-45, 47, 49 and 50, drawn to a method of treating a subject suffering from a disorder of a tissue involving loss or apoptosis of cells of the tissue which comprises administering to the subject a composition comprising an amount of an agent, wherein the agent comprises human stromal-derived factor-1β which induces activation of CXCR4, the composition being administered in an amount effective to cause proliferation of the cells or inhibition of apoptosis of the cells of the tissue within the subject so as to thereby treat the subject, classified in class 514, subclass 1. **Election of this group also requires the further species election of a single disorder from the group consisting of myocardial infarction, congestive heart failure, chronic ischemia, ischemic disease, diabetic heart disease or cardiomyopathy, as explained below AND the further species election of a single mode of administration selected from the group consisting of intramyocardially, systemically, intracoronarily, via a stent, via a scaffold or via slow release formula.**

III. Claims 35-37, 43-45, and 48-50, drawn to a method of treating a subject suffering from a disorder of a tissue involving loss or apoptosis of cells of the tissue which comprises administering to the subject a composition comprising an amount of an agent, wherein the agent comprises human

stromal-derived factor-1γ which induces activation of CXCR4, the composition being administered in an amount effective to cause proliferation of the cells or inhibition of apoptosis of the cells of the tissue within the subject so as to thereby treat the subject, classified in class 514, subclass 1. **Election of this group also requires the further species election of a single disorder from the group consisting of myocardial infarction, congestive heart failure, chronic ischemia, ischemic disease, diabetic heart disease or cardiomyopathy, as explained below AND the further species election of a single mode of administration selected from the group consisting of intramyocardially, systemically, intracoronarily, via a stent, via a scaffold or via slow release formula.**

The inventions are distinct, each from the other because of the following reasons:

Inventions of groups I-III are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed each have different designs and effects, since each group uses a unique compound. The inventions as claimed are mutually exclusive since each method involves a unique agent (human stromal-derived factor-1α, 1β, or 1γ), and therefore

also have at least unique designs. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Species

This application contains claims directed to the following patentably distinct species: myocardial infarction, congestive heart failure, chronic ischemia, ischemic disease, diabetic heart disease or cardiomyopathy. The species are independent or distinct because each has its own unique design that does not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Each also carries its own enablement consideration, the search and examination of which are considered to constitute serious burdens on the Office.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

This application contains claims directed to the following patentably distinct species: single mode of administration selected from the group consisting of intramyocardially, systemically, intracoronarily, via a stent, via a scaffold or via slow release formula. The species are independent or distinct because each has its own

unique design that does not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Each also carries its own enablement consideration, the search and examination of which are considered to constitute serious burdens on the Office.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 35 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is (571) 272-0755.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JON E. ANGELL, PH.D.
PRIMARY EXAMINER

Amy H Bowman
Examiner
Art Unit 1635

AHB